Dura Substitute Guidance Document (Draft)
Questions to the Panel

1. Disease transmission is a potential safety concern whenever tissue-sourced materials are used. FDA currently recommends that processing of dura substitutes comprised of animal-sourced material be validated for elimination of viral, fungal and bacterial contamination.

    a. Please discuss and comment on the types of validation measures to ensure the elimination of contaminants in tissue-sourced dura substitutes.

    b. Please comment and discuss what types of long-term safety information should be gathered.

2. Dura substitutes may be associated with adhesion formation, hemorrhage, and encapsulation/neomembrane formation. In this draft guidance document FDA recommends that clinical trials for dura substitutes follow patients for at least one year at which time the patients are examined clinically, and a CT or MRI scan is performed to determine what changes might have occurred at the implant site. Please discuss the value of imaging studies in assessing the performance of dura substitutes and whether one year is an appropriate time to perform these studies.

3. Patient subpopulations may present unique situations for consideration when dura substitutes are used. For example, tethered cord syndrome patients present different anatomical considerations than trauma patients. In addition, the site of placement and the various sizes of dura substitutes used in duraplasty may influence clinical outcome and the incidence of adverse events. FDA has not recommended that clinical studies be narrowly focused to specific patient cohorts or that clinical trials of dura substitutes study specific anatomic locations in the brain and spinal cord.

    a. Given the potential uses for dura substitutes, e.g., pediatric patients, cancer patients, etc., do you believe that there are specific patient populations that should be studied?

    b. Please comment and discuss whether different anatomic sites of implantation or sizes of dura substitutes need to be evaluated.

    c. This draft guidance document recommends that the clinical effectiveness of dura substitutes be based upon the safety profile of the device, which includes the incidence of adverse events, complications, subsequent surgical interventions and death, and a 1 year CT/MRI scan of the implanted site. Please comment and discuss the appropriateness of these and the following potential endpoints to assess product effectiveness:

        1. CSF leakage;
        2. the ease of device handling including ability to reapproximate the dura;
        3. device conformability to the host tissue; and
        4. degree of adhesion formation.